a pilot project to collect this data and make it available for evaluation and planning processes in a standardized language according to CAP (Catalog for ambulatory procedures). **METHODS:** The data will be transferred into a new database in two data streams to ensure data protection. Data about the patient containing sex, age and other characteristics will be sent in a pseudonomyzed way in one data stream. Another will contain data about the procedures according to CAP and information about contract physicians, outpatient clinics and ambulatories. **RESULTS:** The new database will offer information about what until now has been more or less a black spot. It will give information about procedures performed in the ambulatory and outpatient sector for all stakeholders participating in this pilot project. **CONCLUSIONS:** Data about outpatient clinics and ambulatories have not been made accessible in one database for all participating stakeholders in a standardized language until now. The initiated pilot project and the database created therewith offer an opportunity to cover this lack of information.

CONCEPTUAL PAPERS & RESEARCH ON METHODS – Modeling Methods

PMC12

RULING OUT EXTENDLY DOMINATED OPTIONS USING AN ICER MATRIX

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BACKGROUND: Incremental cost-effectiveness ratios (ICERs) represent the cost per unit of effectiveness of switching to a more costly and more effective option. In reporting results for cost-effectiveness (CE) analyses, options that are strictly dominated are ruled out and no ICERs should be reported. Additionally, some options may be ruled out by extended dominance (i.e., there is a linear combination of two options that dominates an option not otherwise excluded by strict dominance). In order to plot the CE efficiency frontier both strictly and extendedly dominated options must be excluded. Calculating strict dominance (e.g., in Excel) is straightforward. However calculating extended dominance is more complex. **METHODS:** We present a method to exclude extendedly dominated options using an ICER matrix. To form an ICER matrix all options are rank ordered by cost. For a CE analysis with N options, the ICER matrix is an N x N-1 sized table, where the first column represents the ICER from the least costly option to each more costly option, the second column represents the ICER from the second least costly option to each more costly option, etc.. Negative ICERs, representing strictly dominated options, are excluded from the table. Extended dominance is established by calculating whether the ICER for a non-strictly dominated option is greater than the ICER for at least one more costly option. If so, the option is rule out by extended dominance, otherwise not. We show how to perform the required calculations in Excel and how to graphically plot the CE efficiency frontier once all dominated and extendedly dominated options have been excluded. **CONCLUSIONS:** Strictly dominated and extendedly dominated options must be ruled out in order to plot the CE efficiency frontier. The ICER matrix is a systematic method to rule out strictly and extendedly dominated options.

PMC13

THE COST-EFFECTIVENESS SENSITIVITY CURVE: QUANTIFYING THE EFFECT OF INDIVIDUAL PARAMETER UNCERTAINTY IN A PROBABILISTIC MODEL

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BACKGROUND: The cost-effectiveness acceptability curve (CEAC) graphically depicts the joint uncertainty in a probabilistic model by transforming the incremental cost-effectiveness ratio into a net-benefit framework to represent the probability that a strategy is cost-effective over a range of willingness-to-pay (WTP) thresholds. By characterizing the joint distribution of costs and effects for all model parameters, the CEAC simplifies the presentation of uncertainty compared to deterministic one-way and multi-way sensitivity analyses and allows decision makers to identify the preferred strategy based on their WTP threshold. However, in some instances presenting only the joint uncertainty may be a limitation of the CEAC. **METHODS:** We propose a method to graphically present the uncertainty contributed by a single parameter within a probabilistic model called the cost-effectiveness sensitivity curve (CESC). Like the CEAC, the y-axis of the CESC represents the probability that a strategy is cost-effective. However, instead of WTP, the x-axis represents a specified range of values for a single model parameter. The CESC is generated by varying the chosen parameter over the specified range of values and calculating the net-benefit at each value for each simulation based on the sampled values of the remaining model parameters without resampling (note: to effect the net-benefit transformation the CESC is based on a single WTP threshold). Computationally, the CESC requires an additional series of calculations for each simulation corresponding to the desired number of points on the curve. The advantage of the CESC is that it probabilistically describes the effect of uncertainty of a single model parameter on cost-effectiveness. This is particularly useful for ex-ante pricing decisions and for early phase go/no-go decisions based on an anticipated range of effectiveness. **CONCLUSIONS:** The CESC is a useful tool in specific decision making contexts for quantifying the contribution of a single model parameter to uncertainty within a probabilistic model.

PMC14

MEDICATION LABEL EVALUATION PROCESS MODEL: USING THE STRUCTURAL EQUATION MODELING APPROACH TO BETTER PREDICT PURCHASE INTENTION

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OBJECTIVES: The objective of this study was to examine whether the Over-the-Counter Medication Label Evaluation Process Model (OTC-LEPM) or its modified version explained consumer's purchase intention better. **METHODS:** Data collected during an experimental field study was reanalyzed using structural equation modeling (SEM). Purchase intention with regard to three OTC medications for pain was evaluated using simulated product package labels for Acetaminophen, Ibuprofen and Aspirin. The experiment was conducted with consumers in the process of selecting an OTC product at local pharmacy stores. Endogenous variables were product knowledge, product evaluation, attitude-toward-product label and purchase intention. An additional endogenous variable ease of use was used in the modified OTC-LEPM. Demographics collected were analyzed using descriptive analysis in SPSS. AMOS v17 was used to conduct SEM and test whether OTC-LEPM or modified OTC-LEPM was the better model to explain the variables that predict purchase intention. **RESULTS:** A total of 336 consumers participated in the study. A chi-square value using the SEM approach for OTC-LEPM was 6262.390. The SEM for the modified OTC-LEPM indicated that iteration limit was reached (55000). Alternative model approach produced 3 models with slightly better chi-square value. A new model was built by combining alternative model approach and McFadden's Choice Process. This model produced an improved fit, producing a chi-square value of 4697 ($df = 902$, $p < 0.0001$). This model validated that knowledge significantly causes attitude towards product label which directly and indirectly via product evaluation causes purchase intention and these causal links were statistically significant. It indicated that only one exogenous variable age was statistically significant. **CONCLUSIONS:** The modified OTC-LEPM may not be the best model to analyze consumer's OTC medication purchase intention. Further research is needed to evaluate variables that can improve the understanding of consumer's purchase intention.

PMC15

SYNCHRONIZATION OF RANDOM NUMBER STREAMS GREATLY ENHANCES EFFICIENCY OF PROBABILISTIC MODELS

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The inclusion of probabilistic components in health care models requires the implementation of random number sampling. Many microsimulation models use a single simple random number generator without concern for its properties. This limits the modeler's ability to use the identical series of random numbers for alternative treatment strategies or among comparators. Synchronization of model results between treatment arms within a model run is difficult unless separate random streams are used for each source of variation. Synchronization of random number streams requires maintaining arrays of starting and current random number seeds. If each source of variation (e.g., times or probabilities of death and major events) has its own stream then the simulation of identical patients in all treatment arms is possible. By resetting the seed for each arm, the model results are impacted only by differences in model input point estimates (for first-order analyses) or differences in the specified distributions of sampled model inputs (for second-order analyses). The impact of random number sampling is thus maximally correlated between treatments, and the differences in the occurrences of events common to both simulations, e.g., natural death, are not artificially inflated due to random sampling. Given a sufficient number of replications, stochastic models usually produce stable results. This is because any further increase in the number of modeled replications will have minimal impact on the average-based model results. If the modeled result is the ratio of differences, such as an incremental cost effectiveness ratio (ICER), small differences in the denominator often drive the estimate, requiring a large number of replications. The allocation of common events, particularly natural death, to designated random streams minimizes the impact of random sampling on the model results. The number of model replications (and thus execution time) needed to produce stable ICERs may be reduced by as much as 90%.

PMC16

REVIEW OF COST EFFECTIVENESS STUDIES OF HIGH BUDGET IMPACT DRUGS

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OBJECTIVES: The recently made coverage decisions by UK's NICE, Scotland's SMC and the allocation of $1.1Billion for comparative effectiveness research by the United States, are strong indicators of trends in pricing and reimbursement that are likely to be observed in the future. To gain an additional insight into these trends, we analyzed the cost effectiveness studies for the top ten highest selling drugs (~$80–95B worldwide sales). **METHODS:** The Top 10 drugs were selected based on their worldwide sales. For this analysis, we segmented these drugs into categories as primary care, specialty, small molecules, biologics, therapy areas and availability of generic alternatives. We analyzed the cost effectiveness studies that were published in peer-reviewed journals. Search was conducted using generic names of the drugs and the phrase "cost effectiveness" in abstract of the published study. **RESULTS:** During 2003–2008, the number of published studies on "cost effectiveness" have increased by more than 30%. Almost half of the published studies belong to—Remicade, Plavix and Enbrel. There is a large